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Still a tough life for patentees of second-medical-use claims in Dusseldorf – AstraZeneca loses battle against Hexal over Fulvestrant before the Dusseldorf Court of Appeal

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AstraZeneca tried to enjoin Hexal from marketing its *Fulvestrant*-medicament in main proceedings (after already having failed in PI-proceedings) due to alleged patent infringement of AstraZeneca's Swiss-type claim patent. The Dusseldorf Court of Appeal, however, dismissed the appeal (docket-no I-2 U 29/18).

To understand the implications of this case, one has to first step back and take a look at the recent judgments by the 2nd Patent Senate of the Dusseldorf Court of Appeal concerning second-medical-use claims (or respectively, Swiss-type claims).

So what has happened?

It all started in May 2017 when *Östrogenblocker* (in English: "Estrogen Blocker") had been handed down (docket-no I-2 W 6/17). The case can be regarded as a precursor of the *Fulvestrant*-decision as it concerned the PI-proceedings mentioned above. The underlying patent protected the use of *Fulvestrant* in the preparation of a medicament for the treatment of a specific group of patients with breast cancer (i.e. a Swiss-type claim). Based on the *Pemetrexed*-decision of the German Federal Supreme Court (docket-no X ZR 29/15, also known as *Actavis v Eli Lilly*), the Court of Appeal made it clear that Swiss-type claims are to be treated in the same way as so-called EPC 2000-claims. Hence Swiss-type claims are to be regarded as purpose-limited product claims (and not method claims).

According to settled case-law, such claims are not only infringed if the attacked embodiment is directly used in the protected way but also in case of a manifest arrangement. In pharmaceutical cases, this is usually achieved by specific indications within the summary of product characteristics ("SmPC"). However, the Court of Appeal developed a further cause for liability in the absence of a manifest arrangement; namely, a sufficient extent of use (in the patented way) in addition to the infringer's knowledge (or respectively, the infringer's so-called negligent ignorance) about such use (i.e. a subjective element). The Dusseldorf Court of Appeal in its judgment of March 2018 re *Dexmedetomidine* confirmed this reasoning without having to further elaborate on what is meant by "sufficient extent of use". The foundations of this additional cause for liability seems to go back to the Federal Supreme Court re *Antivirusmittel* (docket-no X ZR 51/86) from 1987 indicating that a "practically substantial extent of use" can also be sufficient.

Helpful further guidance by the Court of Appeal in *Fulvestrant*:

Even though the Court of Appeal did not (have to) specify exact numbers as to when a sufficient extent of use can be assumed (rather a patented use in the extent of about 7% was deemed clearly insufficient), the judges gave important guidance as regards two other very important aspects:

1. In pharmaceutical cases, the court assumes that physicians will not prescribe any medicaments outside the scope of the SmPC. Hence, generics companies have to make sure that the protected use is clearly not covered by the SmPC; i.e. merely general indications that do not per se manifestly arrange the product for the patented use (due to its vagueness) can still be the basis for a sufficient extent of use.
2. Furthermore, the sufficient extent of use must still be present at the date of the (latest) oral hearing. For this, the Court of Appeal indicated that one has to assess the last four years prior to the oral hearing.

What does it all mean?

This case-law beginning with *Östrogenblocker* is still rather new and so far other German courts (specifically, Mannheim and Munich) have not yet decided on these issues. The *Pregabalin*-decision by the District Court of Hamburg (docket-no 327 O 67/15) only dealt with the issue of a manifest arrangement based on a participation in rebate schemes of statutory health insurers. It remains to be seen whether these courts (and ultimately, the Federal Supreme Court) will follow the Dusseldorf Court of Appeal. Additionally, it is still not clear what the threshold is for a sufficient extent of use. Likewise, how and if “knowledge” or “negligent ignorance” is to be assessed is also still unanswered.

Until then, patentees who cannot rely on a manifest arrangement bear the burden of proof for arguing sufficient extent of use at the date of the oral hearing. Given the fact that all three decisions in this regard (*Östrogenblocker*, *Dexmedetomidine* and *Fulvestrant*) have been ruled in favour of the defendant (albeit before courts that are usually referred to as being patentee-friendly), this task seems to be rather difficult. Furthermore, generics companies should review and where necessary, amend their SmPCs in order to potentially rule out infringement altogether. Whether this is sufficient is at least questionable (especially in cases of a concurrent participation in rebate schemes in light of the *Pregabalin*-decision).

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This entry was posted on Tuesday, February 5th, 2019 at 10:19 am and is filed under Case Law, Germany, Infringement, Second Medical Use
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